JUN 2 8 2006

K060874 page 1 of 2

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations and the Safe Medical Devices Act of 1990.

510(k) SUMMARY

NAME OF FIRM:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46580

510(K) CONTACT:

Natalie S. Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME:

DePuy Global AP™ Shoulder System

COMMON NAME:

Shoulder Prosthesis

CLASSIFICATION:

Class II, per 21 CFR, 888.3660
Shoulder joint metal/polymer semi-constrained cemented prosthesis
Class II, per 21 CFR 888.3690
Shoulder joint metallic, hemi humeral, uncemented prosthesis

DEVICE PRODUCT CODE:

87 KWS
87 HSD

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Global™ Advantage Shoulder System
Sulzer Anatomical Shoulder System with Removable Heads
Sulzer Orthopedics Anatomica Humeral Stem/Head

DEVICE DESCRIPTION:

The Global AP™ Shoulder Prosthesis consists of individually packaged metal humeral stem, metal head, taper assembly for use in total shoulder arthroplasty. In addition, previously cleared DePuy Global UHMWPE or crosslinked UHMWPE glenoids are used as compatible components in total shoulder arthroplasty.

A Hemi-Shoulder Prosthesis replaces the proximal humerus by either resurfacing the head or using a metal humeral stem and head in hemi-shoulder arthroplasty.

INDICATIONS AND INTENDED USE:

Intended Use:
The subject humeral stem is designed for use as the portion of the shoulder prosthesis that replaces the proximal humerus upon which a prosthetic humeral head is attached to articulate with the natural glenoid fossa or a prosthetic glenoid replacement. The DePuy Global AP™ Shoulder System is intended for cemented and cementless use.

Indications:
Total Shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

The humeral components of the Global AP™ Shoulder are intended for cemented or cementless use as a total or hemi-shoulder replacement.

Glenoid components of the Global AP™ Shoulder are indicated only for use with bone cement for the above indications.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Deformity and/or limited motion.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The Depuy Global AP™ Shoulder System is substantially equivalent to the previously cleared DePuy Global Advantage Shoulder System (K992065), the Sulzer Anatomical Shoulder System with Removable Heads (K030259), and the Sulzer Orthopedics Anatomica Humeral Stem/Head (K990137) based upon intended use, indications for use, design, materials, packaging and sterilization. The subject device does not raise any new issues of safety or effectiveness

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 28 2006

DePuy Orthopaedics, Inc.
c/o Ms. Natalie Heck
Manager, Regulatory Affairs
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K060874
Trade/Device Name: Global AP™ Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Regulatory Class: II
Product Code: KWS, HSD
Dated: June 15, 2006
Received: June 19, 2006

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K06874

Device Name: Global AP™ Shoulder System

Indications for Use:

Total Shoulder or hemi-shoulder replacement is indicated for:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
2. Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

The humeral components of the Global AP™ Shoulder are intended for cemented or cementless use as a total or hemi-shoulder replacement.

Glenoid components of the Global AP™ Shoulder are indicated only for use with bone cement for the above indications.

Hemi-shoulder replacement is also indicated for

1. Ununited humeral head fractures;
2. Avascular necrosis of the humeral head.
3. Deformity and/or limited motion.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Division of General, Restorative, and Neurological Devices

510(k) Number K060874